DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 22, 2015

Alphatec Spine, Incorporated
Ms. Nadine Smith
Senior Specialist, Regulatory Affairs
5818 El Camino Real
Carlsbad, California 92008

Re: K143740
Trade/Device Name: Battalion Universal Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 24, 2015
Received: April 27, 2015

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K143740

K143740

Device Name
Battalion Universal Spacer System

Indications for Use *(Describe)*

The Battalion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as discogenic spinal pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have had at least six months of non-operative treatment. Lumbar DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Battalion System is to be used with autogenous bone graft and supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Phone: (760) 494-6951
Fax: (760) 431-0289

Contact Person: Nadine Smith
Date Prepared: April 24, 2015

II. DEVICE

Name of Device:	Battalion Universal Spacer System
Common or Usual Name:	Spinal Spacer System
Classification Name:	Intervertebral body fusion device (21 CFR 888.3080)
Regulatory Class:	II
Product Code:	MAX

III. PREDICATE DEVICE(S)

Novel® Spinal Spacer System, K080699 (primary predicate)
Lucent® and Lucent Magnum®, K110632 (additional predicate)

IV. DEVICE DESCRIPTION

The Battalion Universal Spacer System is an intervertebral body fusion system. The implants consist of various lengths, widths, heights and degrees of lordosis to accommodate individual patient anatomy. These implants are available in three material varieties: Polyetheretherketone with tantalum markers, commercially pure titanium coated polyetheretherketone with tantalum markers, and titanium alloy. All materials are of surgical grade; polyetheretherketone (PEEK Optima LT1) conforms to ASTM F2026, tantalum conforms to ASTM F560, titanium coating conforms to ASTM F1580, and the titanium alloy (Ti-6Al-4V ELI) conforms to ASTM F136. All implants are provided sterile.

As an accessory, this system includes inserter instruments used to set the implants between the vertebrae. The patient contacting portions of all of these instruments are made of surgical grade stainless steel (17Cr-4Ni) per ASTM A564/A564M. These instruments are provided non-sterile and are intended to be cleaned and steam sterilized before use.

V. INDICATIONS FOR USE

The Battalion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as discogenic spinal pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have had at least six months of non-operative treatment. Lumbar DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Battalion System is to be used with autogenous bone graft and supplemental fixation.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISICS

The technological characteristics of the Battalion implants are substantially equivalent to both predicates in that they are hollow rectangular boxes intended for spinal fixation. Testing demonstrated that the performance capabilities of the Battalion System are substantially equivalent to that of the previously cleared Novel System in K080699. Additionally, the material composition of the PEEK and the Titanium Alloy is substantially equivalent to the Novel System. The material compositions of the Titanium coated PEEK is substantially equivalent to the Lucent and Lucent Magnum in K110632.

VII. PERFORMANCE DATA

The following non-clinical tests support the substantial equivalence determination as discussed in *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*.

Static and dynamic axial compression per ASTM F2077-11
Static and dynamic torsion per ASTM F2077-11
Static and dynamic Shear per ASTM 2077-11
Subsidence Analysis per ASTM F2267-04

Coating Characterization testing was performed using coupons

Static Shear per ASTM F1044-05
Dynamic Shear per ASTM F1160-05
Static Tension per ASTM F1147-05
Abrasion per ASTM F1978-00

VIII. CONCLUSION

The above characteristics and non-clinical tests support the substantial equivalence of the Battalion System to the legally marketed predicates.